### **REMARKS-General**

Applicant has rewritten all claims to define the invention more particularly and distinctly so as to overcome the technical rejections and define the novelty of the invention over the prior art.

# The Objection to The Claims Rejection Under 35 U.S.C. 112

The Office Action stated that the parenthetical subject matter in Claims 1 and 3 rendered the Claims vague and indefinite. The Office Action considered Claim 2 open-ended because of the improper limitation listed. Claims 1-3 were also rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for all skin conditions. The Claims have been rewritten as new Claims 4-8 to define patentability and to better define the weight range of each composition and the specified treatment in the invention.

## The Objection to The Claims Rejection Under 35 U.S.C. 103(a)

The Office Action rejected Claims 1-3 as being unpatentable over Sato et al and in view of <u>Remington's Pharmaceutical Sciences</u>' discussion of the uses of alcohol acetone as solvents.

Sato et al (5,401,741) describes a topical preparation for treating otopathy with a preparation containing ofloxacin or a salt. The preparation does not include alcohol or acetone. The patent refers to the treatment of diseases of the ear with otitis media,

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inflammation of the inner ear, and otitis externa, inflammation of the outer ear, through the use of a fluoroquinolone antibiotic. This patent does not conflict with the Application for a fluoroquinolone and alcohol and acetone combination because they treat areas of the human body that are not comparable. In addition, the fluoroquinolone and alcohol and acetone combination mixes together different active ingredients than the Sato et al patent.

The Office Action also lists <u>Remington's Pharmaceutical Sciences</u> as an indication that alcohol and acetone are proven solvents in pharmaceutical applications. Dermatologists have used these ingredients in topical applications, as seen in Seba-Nil, a skin cleanser that combines both alcohol and acetone. In addition, no prohibition has been placed on granting patents to mixtures that combine an antibiotic with alcohol and acetone in a unique combination. Robinson et al (5,409,917) describes the use of a cephalosporin antibiotic in an alcohol base for the treatment of acne and acneiform dermal disorders.

Fluoroquinolones and alcohol and acetone have been tested and utilized for years in the treatment of acne but have never been combined into one topical application. The Applicant put them into one topical application to take advantage of the improved antibiotic activity seen when fluoroquinolones and alcohol and acetone are combined together. With this topical application, a large amount of the antibiotics will be absorbed by the skin and brought into the blood stream of the patient, thus reducing the acne pustules and the bacteria found on the skin. In addition, both active ingredients have unique properties that work well together. Mixing the fluoroquinolone antibiotic will provide the patient with an additional cleansing agent for dissolving oil build-up on the

skin. The combination of these three ingredients will not dilute the effectiveness of the two active ingredients. By combining these two active ingredients, the Applicant has invented a new and unique topical treatment for acne and other skin disorders.

Under the terms of the 14<sup>th</sup> Amendment to the U.S. Constitution, which states, "equal protection of the laws," a patent given to another person for combining ingredients should also be given for the unique combination of fluoroquinolones and alcohol and acetone presented in this Application.

### Conclusion

For all the reasons given above, the applicant respectfully submits that the errors in the Claims comply with Section 112 and the Claims define over the prior art under Section 102 because the Applicant has shown evidence that the combination does not conflict with the Sato et al patent and the Applicant has shown that the fluoroquinolone and alcohol and acetone mixture are a unique topical combination. Accordingly, Applicant submits that this application is now in full condition for allowance, which action Applicant respectfully solicits.

## **Conditional Request for Constructive Assistance**

Applicants have amended the Claims of this application so that they are proper, definite, and define novel structure which is also unobvious. If, for any reason this application is not to be believed in full condition for allowance, Applicant respectfully requests the constructive assistance and suggestions of the Examiner pursuant to MPEP 706.03(d) and

707.07(j) in order that the undersigned can place this application in allowable condition as soon as possible and without the need for further proceedings.

Very respectfully,

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Certificate of Mailing: I certify that on the date below this document and referenced attachments, if any, will be deposited with the U.S. Postal Service as certified mail in an envelope addressed to: "ATTN: P. Spivak, GAU 1614, Box Non-Fee Amendments, Assistant Commissioner for Patents, Washington DC 20231."

1998 November 14

Letantia Bussell, Applicant